Title 33
ENVIRONMENTAL QUALITY

Part I. Office of the Secretary
Subpart 3. Laboratory Accreditation

Chapter 45. Policy and Intent

§4501. Description and Intent of Program

A. These regulations provide requirements for an accreditation program specifically applicable to commercial laboratories and federal, state, and local government laboratories performing analyses reportable to the Louisiana Department of Environmental Quality (the Department). The department laboratory accreditation program is designed to ensure the accuracy, precision, and reliability of the data generated, as well as the use of department-approved methodologies in the generation of that data. Laboratory data generated by commercial environmental laboratories that are not accredited under these regulations will not be accepted by the department.

B. This accreditation covers the following fields of testing:

1. air emissions;

2. wastewater/surface water;

3. groundwater;

4. solid/hazardous wastes;

5. soils, sediments, and sludges;

6. biological materials;

7. radiologicals/radioassays; and

8. bioassays/biomonitoring/toxicological testing.

C. Each field of testing is divided into test categories. Applications for accreditation may be made for one or more test categories within specified fields of testing. To apply the laboratory must identify the specific department-approved methods it will be using for each test category and participate in all relevant department-approved proficiency testing programs. Any variance from approved protocol or procedure is acceptable only with prior written confirmation by the department.

D. Applicants must have an acceptable quality control system and associated documentation. Accreditation earned from other states or regulatory agencies may be accepted by the department, provided that a review shows that the requirements are no less stringent than those required by these regulations. Reciprocity with other state accreditation programs will be reviewed by the department, and if the requirements of these regulations are met, then accreditation may be granted.

E. This Subpart shall not apply to laboratory analyses programs accredited under the regulatory and statutory authority of the Louisiana Department of Health and Hospitals.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of the Secretary, LR 24:_____.

§4503. Definitions

When used in these rules and regulations, the following words and phrases shall have the meanings ascribed to them below:

Accreditation—the formal recognition by the department of a laboratory's competence wherein specific tests or types of tests can be accurately and successfully performed in compliance with all minimum requirements set forth in these regulations.

Annual Renewal Date—July 1.

Applicant—the laboratory requesting accreditation.

Commercial Laboratory—any laboratory that performs analyses or tests for third parties for a fee or other compensation, except those commercial laboratories accredited by the Department of Health and Hospitals in accordance with R.S. 49:1001 et seq.

Department—the Louisiana Department of Environmental Quality.

Department Accreditation Program—a program instituted by the department by which a laboratory that generates data for submittal to any area of the department may be deemed an accredited laboratory producing acceptable data, based upon the accuracy and reliability of the generated data, the use of department-approved methodology for the generation of the data, and the utilization of an acceptable quality control/quality assurance program to document the quality of the data produced.

Department-Approved Testing Methods—the laboratory and field procedures that have been approved by the department. These include all EPA-recognized methods, as well as those deemed equivalent by the department, that are adopted from existing standards and regulations or

developed for specific fields of testing, specific testing technologies, or specific types of tests. This refers to the methods cited in the 40 CFR and subsequent changes published in the *Federal Register* from such sources as U.S. EPA, *Standard Methods for the Examination of Water and Wastewater,* ASTM, NIOSH, SW-846, *American Public Health Association for Microbiological Methods,* USGS, AOAC, and alternate test procedures approved for use.

Discreditation—the revocation by the department of the formal recognition of the laboratory's accredited status because of a violation of LAC 33:I.5705.F.

EPA—the United States Environmental Protection Agency.

EPA-Accepted Methods—the methods cited in the 40 CFR and subsequent changes published in the *Federal Register*; from such sources as EPA, *Standard Methods for the Examination of Water and Wastewater*, ASTM, NIOSH, SW846, *American Public Health Association for Microbiological Methods*, USGS, AOAC, and alternate test procedures approved for nationwide use, as well as any method approved by the department.

Field of Testing—air emissions; wastewater/surface water; groundwater; soils, sediments, and sludges; solid/hazardous wastes; biological materials; radiologicals/radioassays; and bioassays/biomonitoring/toxicological testing.

Laboratory—any facility, whether fixed-based, mobile, or field, that analyzes environmental samples and that seeks accreditation by the department.

Laboratory Representative—the laboratory employee who is designated as the contact person responsible for the information provided in the application and for ensuring compliance with the requirements for accreditation.

Mobile Laboratory—any facility that analyzes environmental samples and that seeks accreditation by the department that is capable of moving or being moved from one site to another.

NIST—National Institute of Standards and Technology.

NRC—Nuclear Regulatory Commission.

Pending Accreditation—a status that exists in the accreditation process wherein all application requirements have been met by the laboratory, but formal accreditation status has not been granted by the department.

Proficiency Evaluation Test Sample (PE)—a sample of known composition (unknown to laboratory) provided by an external source (e.g., EPA) that is used to evaluate lab performance.

Reaccreditation—the reinstatement of a fully accredited status by the department, thereby signifying that all violations of LAC 33:I.5705.F that initiated the discreditation action have been corrected and that the laboratory is deemed in compliance with requirements of these regulations.

Reciprocity—a method of obtaining accreditation, whereby the applicant laboratory provides documentation that demonstrates that its current certification or accreditation is no less stringent than required by these regulations. All fees associated with accreditation in the state of Louisiana shall be applicable. Laboratories located within the state of Louisiana shall be required to apply for a certification and shall not be eligible for reciprocity.

Round Robin Testing—a method of proficiency testing, whereby a blind sample is split and sent to laboratories for analysis from the department or its representative. Laboratories participating in round robin testing shall not pass test samples from one laboratory to another. This form of testing shall be limited to use where applicable.

Small Laboratory—a laboratory consisting of 10 or fewer people who influence the quality of data from sample collection through report generation.

Suspension—a temporary removal by the department of the accredited status, in part or whole, of a laboratory because of an infraction(s) of LAC 33:I.5705.F until such time that the infraction(s) is satisfactorily corrected and the laboratory is returned to a fully accredited status or the infraction(s) is not corrected and the laboratory is discredited.

Test Category—any one of the 10 categories listed in LAC 33:I.4705.B in which a laboratory may request department accreditation for a specific test or analysis.

Variance—any deviation from a department-approved method that has the potential for affecting the analytical results generated from a test procedure.

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Title 33
ENVIRONMENTAL QUALITY

Part I. Office of the Secretary
Subpart 3. Laboratory Accreditation

Chapter 47. Program Requirements

§4701. Accreditation Process

A. The department accreditation process comprises four basic steps:

1. the submittal to the department of a written request from the laboratory in the form of an application provided by the department, along with payment of all applicable fees;

2. an on-site assessment/evaluation of the laboratory submitting the request/application by authorized representatives of the department with the appropriate laboratory background;

3. the successful participation in department-approved applicable proficiency evaluations; and

4. both periodic technical evaluation of the laboratory and periodic submittal by the laboratory of written documentation that all requirements of the department accreditation program are being fulfilled in order to maintain accreditation.

B. When all requirements for accreditation have been successfully fulfilled, the department shall grant the applicant laboratory a formal notice of accreditation and a certificate of accreditation that lists those parameters for which the laboratory is accredited. The certificate of accreditation must be posted within public view in the laboratory setting.

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HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of the Secretary, LR 24.

§4703. Application for Accreditation

A. An applicant for environmental laboratory accreditation must be legally identifiable and possess a permanent business address and telephone number. The applicant laboratory must have the staff and

resources in order to satisfactorily accomplish those analyses/tests for which accreditation is requested.

B. An application for environmental laboratory accreditation shall be made in writing to the department. This application will provide all requested information and be accompanied by the appropriate application fee. Information will include at least one satisfactory round of the most recent department-specified proficiency evaluation test results or an analytical data package for test categories where no accessible proficiency tests exist. Supplemental information may be required.

C. Laboratories maintained on separate premises, even though operated under the same management, shall be required to maintain distinct accreditation. If a laboratory is located outside of the state of Louisiana, it shall be considered a separate and distinct laboratory and shall require individual accreditation. Separate accreditation is not required for buildings on the same or adjoining grounds. If a mobile laboratory is operating independently within the state, separate accreditation may be necessary.

D. Each laboratory must identify an official to represent it in all matters related to attaining and maintaining environmental laboratory accreditation. This official is the point of contact with the laboratory and is known as the laboratory representative. The laboratory representative may be any senior person from either the technical or managerial staff. The laboratory representative should be in a position of authority to ensure that the laboratory complies with the criteria and conditions for accreditation and should have the authority to bind the company in a legal manner.

E. In cases where all application requirements have been met, including review of all methodology and quality assurance program data, a special status of "pending accreditation" may be granted at the discretion of the department. Before a laboratory is granted full accreditation, all requirements of these regulations must be met.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of the Secretary, LR 24.

§4705. Categories of Accreditation

A. At the time of application each applicant must clearly identify both the fields of testing and the test categories for which accreditation is sought. A copy of the relevant test method documentation and the requisite equipment for the method must be available at the laboratory. A current list of approved methodologies for each parameter/analyte will be maintained by the department accreditation office, and a copy of the list will become a part of the

application package. In cases were the methodology used by the laboratory is not listed, the laboratory shall submit documentation that will verify that the results obtained from the method in use are equal to or better than those results obtained from the approved methodology. The department will review the data submitted by the laboratory and will notify the laboratory in writing within 60 calendar days if the method is acceptable or unacceptable as an alternate method of analysis.

B. A laboratory may apply for accreditation in any one or more of the eight fields of testing (e.g., air emissions, wastewater/surface water, etc.) and in one or more of the 10 test categories applicable to the field(s) of testing selected. The laboratory shall be accredited in those parameters within the test category(ies) for which the laboratory demonstrates acceptable performance on proficiency samples (when available) and meets all other requirements of the department accreditation program. The accreditation test categories are as follows:

1. metals;

2. air pollutants (including industrial hygiene and Toxic Organic Compounds (T.O.) methods);

3. nutrients, minerals, ions, demands, classical wet chemistry, and total and fecal coliform;

4. microbiology (including fecal coliform and total coliform);

5. bioassay and biomonitoring;

6. organics (including volatiles, semi-volatiles, pesticides, herbicides, and PCBs);

7. dioxins and furans;

8. radiochemistry and radio assay;

9. asbestos; and

10. minor conventional parameters - BOD_5, oil and grease, TSS, pH, fecal and total coliform, and residual chlorine.

C. An accredited laboratory may request the addition of field(s) of testing and test category(ies) to its scope of accreditation at any time. Such a request must be submitted in writing to the department. Unless the previous on-site inspection can verify the competence of the laboratory to perform the additional tests, another on-site inspection may be required.

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§4707. Fees

A. Testing laboratories applying for accreditation or renewal of accreditation shall submit the appropriate fee calculated from the fee schedule along with the required application or update materials. Fees are nonrefundable. Fees are based on test categories and not the fields of testing.

B. In-house laboratories owned and/or operated by the state, local, or federal government are exempt from the fee requirements paid to the department, but shall make appropriate application for accreditation in accordance with other provisions of these regulations. Required proficiency samples shall be purchased by the laboratory and the required third party audit shall be billed directly to the laboratory.

C. The annual fees shall not be prorated and shall apply in full to any portion of the fiscal year that remains prior to the annual renewal date (July 1).

D. The following basic fee structure will be used in determining the initial or annual fees due to the department:

Accreditation application fee payable every three years	$500.00
Per major test category payable every year	$250.00
Minor conventional category payable every year	$200.00
Annual surveillance and evaluation applicable to minor conventional facilities and facilities applying for only one category of accreditation	$250.00
Proficiency samples biannually	to be purchased by the laboratory
Bioassay/biomonitoring annually	to be purchased by the laboratory
Third-party audit	to be billed directly to the laboratory

E. Additional fees may be charged for the expansion of accreditation to include new test categories. Fees must be received prior to granting accreditation. Fee assessment will depend on the category(ies) of analyses and the need for a supplemental on-site inspection.

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§4709. Inspection of Laboratory

A. As a condition of obtaining and maintaining accreditation, a laboratory shall permit and facilitate inspections by personnel or designated representatives of the department. The specific requirements of an on-site inspection are outlined in LAC 33:I.Chapter 51.

B. Inspectors shall conform to appropriate safety procedures during an on-site inspection. The authorized representatives of the department who perform the on-site evaluation must be experienced professionals and hold at least a bachelor's degree in a science-related field with technical experience in a laboratory. The representative(s) must successfully complete a laboratory certification course presented by the United States Environmental Protection Agency, the National Institute of Standards and Technology, or other department-approved training group.

C. Regular inspections of accredited laboratories shall be conducted at intervals of not more than two years. Such inspections shall be conducted by representatives of the department upon presentation of credentials. Prior to granting initial accreditation and after all documentation provided to the department has been reviewed, an announced on-site laboratory inspection shall be performed.

D. Inspections may include on-site proficiency test sample(s) analyses but shall not exceed 10 percent of the test ~~category(ies)~~ parameter(s) but must maintain minimum of one test. If there is a cost for these samples, the department will bill the laboratory, and the laboratory shall remit within 30 calendar days.

E. Laboratories that utilize mobile and/or field laboratories shall not be required to certify each laboratory individually. The mobile and/or field facilities shall be considered a part of the fixed-based laboratory and shall be required to participate in performance evaluation studies. Mobile and/or field laboratories shall not be exempt from any applicable requirements of an on-site evaluation as outlined in LAC 33:I.Chapter 5l. Mobile and/or field laboratories may be inspected at the discretion of the department. In the event an organization is composed entirely of mobile and/or field laboratories and no fixed-based laboratory exists, the business address of the organization shall be utilized as the location for accreditation purposes.

F. Fixed-base laboratories that have moved to a new location shall be inspected within 30 calendar days after the laboratory has notified the department, in writing, of such change in location as required in LAC 33:I.5707.

G. The department shall reserve the right to inspect or observe the testing procedure(s) of the laboratory if such action is deemed necessary by the department.

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HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of the Secretary, LR 24.

§4711. Proficiency Testing Participation

A. All accredited environmental laboratories or laboratories seeking accreditation must participate in department-approved proficiency testing programs relevant to their scope of accreditation, except when determined by the department that an appropriate proficiency test is not accessible or readily available. The department may provide appropriate commercial test samples at the applicant's expense whenever necessary.

B. If proficiency test samples are not available for particular test categories, the laboratory requesting accreditation will submit an "analytical data package." An "analytical data package" shall include all relevant analytical methodology, technical information, and quality assurance results concerning a particular type of analysis for which there is no current proficiency testing program.

C. Department-approved proficiency tests shall be used to provide suitable evidence of laboratory proficiency.

D. Proficiency testing studies will be available at a minimum of every six months. Laboratories may set up round robin testing programs under the department’s supervision in order to satisfy this requirement, using splits where ~~appropriate~~ applicable.

E. Laboratories shall satisfactorily analyze at least one of the two proficiency test studies offered per year for each test category accredited. A year shall be considered as the 12-month period from the first day of July until the last day of June. Results shall be considered satisfactory when they are within the acceptable limits established by the testing agency or the department.

F. Each participating laboratory must supply the department with a copy of the proficiency evaluation (PE) test results within 30 days of receipt by the laboratory. Every laboratory that receives test results that are "unacceptable" for a specific analyte must investigate and identify likely causes for these results, resolve any problems,and report such activity to the department along with the submittal of test results.

G. In cases of on-site proficiency testing, the department shall inform the laboratory of the results of the evaluation. The department

may require the laboratory to analyze additional proficiency samples if the results of such test are “unacceptable.”

H. Results of proficiency testing during the preceding 12 months shall be made available by the laboratory, upon request, to any person utilizing or requesting the services of the laboratory.

I. Accredited laboratories that desire to extend the range of tests or analyses offered shall submit a written request with the appropriate fees, shall comply with the requirements of these regulations, and shall demonstrate satisfactory results in at least one round of proficiency testing samples prior to receiving accreditation.

J. Laboratories shall bear the cost of any subscription(s) to a proficiency testing program required by the department for compliance purposes.

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§4713. Interim Acceptance of Accreditation by Another Accrediting Authority for In-State Laboratories

A. Acceptance of accreditation from another accrediting authority as equivalent accreditation shall be determined by the department.

B. All of the following requirements must be fulfilled:

1. a completed application form and support documents submitted;

2. any appropriate fee(s) paid;

3. evidence of successful participation in a proficiency testing program or its equivalent;

4. written documentation of accreditation sent to the department;

5. a comparison of certification requirements from the accredited laboratory; and

6. an on-site evaluation/inspection conducted by authorized representatives of the department or the previous inspection conducted by the accrediting authority.

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HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of the Secretary, LR 24.

§4715. Accreditation for Laboratories not Located in Louisiana

A. Out-of-state laboratories may receive accreditation via two mechanisms:

1. direct application to the department based on the requirements of this program; or

2. reciprocity based on evaluation of current accreditation maintained. Reciprocal accreditation is based on meeting the requirements set forth in LAC 33:I.4713.

B. A testing laboratory located outside of Louisiana may receive accreditation from the department or from another agency having environmental regulatory responsibility or delegated administrative authority, if approved by the department. The laboratory shall comply with all documentation and fee requests from the department.

C. If the out-of-state laboratory's accreditation is revoked, the Louisiana authorization is thereby automatically canceled. The environmental representative shall notify the state and all clients in Louisiana that utilize the laboratory of the revocation within 10 calendar days.

D. When accreditation of the laboratory has been reinstated, the department will request adequate documentation from the laboratory indicating that the laboratory is in compliance with these regulations. The following requirements must be fulfilled before the department reinstates the laboratory as accredited:

1. a completed application form and support documents submitted;

2. fee(s) paid in accordance with LAC 33:I.4707;

3. evidence of successful participation in a proficiency testing program or its equivalent;

4. written documentation of accreditation sent to the department; and

5. an on-site evaluation/inspection conducted by authorized representatives of the department.

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§4717. Accreditation for Laboratories Participating in the NELAP Certification Program

In-state laboratories participating in the National Environmental Laboratory Accreditation Program (NELAP) shall be certified under standards established by these regulations and those of the NELAP program as found at http://134.67.104.12/html/nelac/standards.htm or by writing NELAP, U.S. Environmental Protection Agency (MD-75A), Research Triangle Park, NC 27711, attention: NELAC Director, telephone (919)541-1120. NELAP-certified laboratories shall be required to meet the requirements for reciprocity as set forth in LAC:33:I.4713.

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§4719. Implementation

A. All commercial laboratories analyzing data as of the effective date of these regulations that are directly or indirectly submitting data to the department must submit an application for accreditation as required in LAC 33:I.4701.A.1, including the review fee, within 180 days of the effective date of these regulations. The department will not accept laboratory data generated by laboraties that do not comply with this deadline until such laboratories receive accreditation and fully comply with the requirements of this Section.

B. All laboratories subject to these regulations must receive accreditation from the department, as provided in these regulations, undergo an on-site inspection as specified in LAC 33:I.4701.A.2, and successfully participate in proficiency evaluations as required in LAC 33:I.4701.A.3 within one year of the effective date of these regulations. The department will not accept data generated by laboratories that do not comply with this deadline until such laboratories receive accreditation and fully comply with the requirements of this Section.

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Title 33
ENVIRONMENTAL QUALITY

Part I. Office of The Secretary
Subpart 3. Laboratory Accreditation

Chapter 49. Organization and Personnel Requirements

§4901. Laboratory Staff for All Programs Covered by these Regulations

A. Managerial Staff. The laboratory shall have the managerial staff with the authority and resources needed to discharge their duties. The laboratory shall be organized in such a way that confidence in its independence of judgment and integrity is maintained at all times. The laboratory shall specify and document the responsibility, authority, and interrelation of all personnel who manage, perform, or verify work affecting the quality of calibrations and tests. Such documentation shall include:

1. a clear description of the lines of responsibility in the laboratory;

2. personnel proportioned such that adequate supervision is ensured. An organizational chart is recommended; and

3. job descriptions for all positions.

B. Laboratory Technical Director

1. Academic Training. The laboratory technical director must have a bachelor's degree in science or a minimum of four years' equivalent experience in a related field.

2. Experience. The laboratory technical director must have a minimum of two years' experience in the area of environmental analysis.

C. Quality Assurance Manager

1. Academic Training. The quality assurance manager must have a minimum of a bachelor's degree in science or four years' equivalent experience in a related field.

2. Experience. The quality assurance manager must have a minimum of two years' environmental laboratory experience.

3. Reporting Authority. The quality assurance manager must have direct access to the highest level of management for decisions

regarding laboratory quality assurance policy and resources. He or she must have independent authority regarding quality assurance oversight and implementation of the quality assurance program. This organizational position must not report through the technical management of the laboratory. The quality assurance manager must have the opportunity and freedom to evaluate data objectively without influence from technical or financial management.

4. Technical Knowledge. The quality assurance manager must have a general knowledge of all analytical methods that are performed by the laboratory.

5. Small Laboratories. In smaller laboratories (staff less than 10 total employees), the quality assurance manager's responsibilities may be performed by an upper level technical or operational manager of the facility. Academic and experience requirements apply.

D. Supervisors

1. Academic Training. Supervisors must have a minimum of a bachelor's degree or a minimum of four years' experience in a related field.

2. Experience. Supervisors must have a minimum of one year of experience in the area to be supervised, preferably with a minimum of six months' supervisory experience.

3. Radiochemistry. If the individual is supervisor of a radiochemistry laboratory, the individual must have a minimum of four years' experience in the field/area of radiochemistry; however, each year of additional college-level training in related fields may substitute for one year of experience, up to a maximum of two years.

E. Instrument Operators

1. Academic Training. Instrument operators must have a minimum of a high school diploma or equivalent and satisfactory completion of a short course or structured in-house equivalent on the operation of the instrument (by equipment manufacturer, professional organization, university, or other qualified training facility).

2. Experience. Instrument operators must have a minimum of six months' experience in the operation of the instrument with documentation that acceptable results are achieved by the operator (performance evaluation and quality control samples successfully analyzed).

3. On-the-Job Training. During on-the-job training to fulfill the requirement for experience, the data produced by the operator shall be deemed acceptable when validated and reviewed by a qualified instrument operator and/or laboratory supervisor.

F. Analyst

1. Chemistry Procedures

a. Academic Training. An analyst must have a minimum of a high school diploma or equivalent, plus proper training in a methods training course or by a qualified analyst.

b. Experience. An analyst must have a minimum of six months' laboratory experience with the analysis procedure(s) with documentation that acceptable results are achieved by the analyst (performance evaluation and quality control samples successfully analyzed).

c. On-the-Job Training. During on-the-job training to fulfill the requirement for experience, data produced by the analyst shall be deemed acceptable when validated and reviewed by a qualified analyst and/or laboratory supervisor.

2. Microbiological Procedures

a. Academic Training. An analyst must have a minimum of a bachelor's degree in science or four years' experience in a related field. He or she must have training in water analyses for total coliform and fecal coliform, a minimum of a high school diploma, or the equivalent, and satisfactory completion of a short course or structured in-house equivalent on the proper techniques of analysis.

b. Experience. An analyst must have a minimum of six months' experience in microbiological analysis and techniques.

3. Radiological Procedures (Gross Alpha, Gross Beta, and Specific Radionuclides)

a. Academic Training. An analyst must have a minimum of a high school diploma or equivalent, plus specialized training in standards and sample preparation, instrument calibration, calculations, and data handling.

b. Experience. An analyst must have a minimum of six months of on-the-job training. An analyst may assist in routine sample preparation and radioanalytical procedures provided that the work is supervised and validated by a qualified analyst and/or laboratory supervisor.

4. Biomonitoring Procedures

a. Academic Training. An analyst must have a minimum of a high school diploma, or the equivalent, and documented training by a qualified analyst. EPA video training tapes should be utilized where available.

b. Experience. An analyst must have six months of on-the-job training with documentation of acceptable results from standard reference toxicant tests performed by the analyst.

c. On-the-Job Training. During on-the-job training to fulfill the requirements for experience, data produced by the analyst shall be deemed acceptable when validated and reviewed by a qualified analyst and/or laboratory supervisor.

G. Information on the relevant qualifications, training, and experience of the technical staff shall be maintained by the laboratory.

H. The laboratory shall provide additional training as needed in order to keep personnel current with new procedures, changes in existing procedures, and/or equipment changes or improvements.

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Title 33
ENVIRONMENTAL QUALITY

Part I. Office of the Secretary
Subpart 3. Laboratory Accreditation

Chapter 51. On-site Inspection/Evaluation

§5101. Inspection Procedures

A. The authorized representative(s) of the department shall schedule the initial on-site inspection with the applicant laboratory. The authorized representative(s) of the department may make an announced or unannounced inspection or examination of an accredited laboratory whenever the department, in its discretion, considers such an inspection or examination necessary to determine the extent of the laboratory's compliance with the conditions of its accreditation and these regulations. Any refusal to allow entry to this representative shall constitute a violation of a condition of accreditation and is grounds for discreditation. The laboratory shall provide appropriate safety equipment for the department representative(s) when required.

B. Additional inspections may be conducted when evaluations and submissions from the laboratory or its clients indicate significant technical changes in the capability of the laboratory have occurred.

C. The following shall be available for review at the laboratory:

1. quality assurance plan;

2. approved methodology manual;

3. quality assurance data; and

4. proficiency test data.

D. During inspections, consideration will be given to:

1. competence of the staff;

2. working conditions, including adequacy of space;

3. lighting, equipment, and supplies;

4. efficient organization of the laboratory;

5. testing or analytical methods used;

6. quality control procedures;

7. maintenance of all required records; and

8. compliance with all the requirements of these regulations.

E. Laboratory inspection will follow this general outline:

1. an entry briefing with laboratory management;

2. review of quality documentation, sample handling, and records, such as typical lab results and reports of test data;

3. interviews with technical staff;

4. demonstration of selected tests, as necessary;

5. examination of equipment and calibration records;

6. an exit briefing including the specific identification of any deficiencies; and

7. a written report of inspection findings to be forwarded to the laboratory within 60 working days after the on-site visit.

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HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of the Secretary, LR 24.

§5103. Laboratory Facilities

A. The laboratory conditions in which the tests are undertaken shall not invalidate the test results or adversely affect the required accuracy of measurement. The laboratory shall have the equipment and energy sources needed for proper testing. They shall be equipped with devices to monitor essential environmental conditions. Specifically, the testing laboratory shall include the following:

1. adequate work space, ventilation, light, and access to stable power sources at work stations;

2. exhaust hoods for proper elimination of volatile materials;

3. contamination-free work areas as necessary;

4. chemical and sample handling areas that will provide safe working areas and prevent cross contamination of samples;

5. adequate storage facilities for samples, extracts, reagents, solvents, reference materials, and standards to preserve their identity, concentration, purity, and stability;

6. adequate procedures and facilities in place for collection, storage, and disposal of wastes;

7. where relevant, adequate procedures and facilities for handling materials that may transmit infectious agents and radioactive materials;

8. appropriate storage for volatile, corrosive, or explosive chemicals and flammable solvents;

9. adequate separation of activities to ensure that no activity has an adverse effect on analyses;

10. separate culturing and testing facilities for biomonitoring laboratories; and

11. counting rooms that are physically separated from other activities in radiological laboratories.

B. Access to and use of all test areas shall be regulated in a manner appropriate to their designated purpose, and entry by persons external to the laboratory shall be controlled.

C. Adequate measures shall be taken to ensure cleanliness in the testing laboratory.

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§5105. Test Methods and Procedures

A. The testing laboratory shall have adequately documented instructions on the use and operation of all relevant equipment, on the handling and preparation of test items, where applicable, and on standard testing techniques, where the absence of such instructions could jeopardize the efficiency of the testing process. All instructions, standards, manuals, and reference data relevant to the work of the testing laboratory shall be maintained up-to-date and be readily available to the staff.

B. The testing laboratory shall use department-approved methodologies. These methodologies shall be available to the staff performing the tests.

1. Any variance from department-approved methodology is acceptable with prior written confirmation by the department. When an approved method or an appropriate modification is not available, the data may be accepted when submitted with the method validation package that must include, at a minimum, the requirements found in Subsection B.2 of this Section.

2. Where it is necessary to deviate from department-approved methods, a method validation package shall be submitted. This validation package must include, at a minimum, the following:

a. origin of method;

b. deviations from standard;

c. reason for deviations;

d. effects of deviations; and

e. comparison with the department-approved methods replaced, with documentation indicating results achieved from the modified method are equal to or better than the original method.

C. Any federal and/or state regulations applicable to the request for alternate methodology shall have priority over these regulations, and shall be utilized in the assessment of the request.

D. The testing laboratory shall have implemented the written standard operating procedures (SOPs), which shall be available to the staff and the inspector.

E. The testing laboratory shall have an acceptable and written quality assurance program plan that is implemented by the staff and readily available to the inspector.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.
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§5107. Deficiencies Identified During On-Site Inspection

A. Whenever deviations or deficiencies are found during an inspection, documentation of same will be included in the written report as required in LAC 33:I.5101.E.7. The laboratory representatives (or designees) will be asked to attest to (sign) receipt of the on-site inspection form and review same with the representative of the department conducting the inspection. The laboratory shall have a period of 30 calendar days from date of receipt of the laboratory inspection report in which to respond to the deficiencies reported and submit a plan for correcting all identified deficiencies. If the laboratory fails to respond, the accreditation process will terminate and the laboratory will be considered as nonaccredited.

B. The laboratory shall correct any deficiencies or deviations within six months from the date of receipt of the inspection report. If deficiencies affecting the accuracy of results are found, the accreditation shall be immediately suspended or revoked.

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§5109. Report of On-Site Inspection

A. The department shall prepare for each accredited laboratory a listing of the test categories for which the laboratory has demonstrated proficiency during inspections. Inspection reports and listings shall be deemed public records. The department shall prepare a certificate of accreditation identifying the test categories for which the laboratory has been approved.

B. Whenever an accredited laboratory completes the requirements for increasing the scope of accredited analyses performed, another on-site inspection may be required, unless the previous annual on-site

inspection verifies the competency of the laboratory to perform the additional tests.

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§5111. Laboratory Safety Program

While specific safety criteria are not an aspect of laboratory accreditation, laboratory personnel should apply general and customary safety practices as part of good laboratory procedures. Each laboratory is strongly encouraged to have a written safety plan as part of their standard operating procedures. However, when safety practices are included in any approved method, those procedures become mandatory and must be strictly followed.

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Title 33
ENVIRONMENTAL QUALITY

Part I. Office of the Secretary
Subpart 3. Laboratory Accreditation

Chapter 53. Quality System Requirements

§5301. Quality Assurance/Quality Control Requirements

A. Each laboratory seeking accreditation shall:

1. have documented quality control procedures in use for each analytical procedure;

2. comply with all quality control procedures required by applicable federal, state, or public health agencies when performing analyses; and

3. have procedures to be followed for feedback and corrective action whenever testing discrepancies are detected or departures from documented policies and procedures occur.

B. The laboratory shall operate an internal quality assurance program appropriate to the type, range, and volume of work performed. A person/persons having responsibility for quality assurance within the laboratory shall be designated by the laboratory management and have direct access to top management.

C. The quality assurance program shall be documented in a quality assurance manual that is available for use by the laboratory staff. The quality assurance manual shall be maintained by the quality assurance manager. The quality assurance manual shall contain information regarding:

1. the structure of the laboratory (organizational charts and generic position descriptions);

2. the operational and functional duties and services pertaining to quality assurance, so that each person concerned knows the extent and the limits of his/her responsibility;

3. general quality assurance procedures;

4. procedures for feedback and corrective action whenever testing discrepancies are detected;

5. chain of custody procedures;

6. a quality policy statement, including objectives and commitments, by management;

7. references to procedures for the control and maintenance of documentation, including document control of laboratory notebooks, instrument logbooks, standards logbooks, and records for data reduction, validation, storage, and reporting;

8. the laboratory’s procedures for achieving traceability of measurements;

9. the laboratory’s scope of tests;

10. references to procedures for handling submitted samples;

11. references to major equipment, as well as the facilities and services used by the laboratory;

12. references to procedures for calibration, verification, and maintenance of equipment;

13. references to verification practices including interlaboratory comparisons, proficiency testing programs, use of reference materials, and internal quality control schemes;

14. the laboratory management arrangements for departures from documented policies and procedures or from standard specifications;

15. references to procedures for dealing with complaints;

16. references to procedures for protecting confidentiality and proprietary rights;

17. references to procedures for audit and review; and

18. references to processes/procedures for establishing that personnel are adequately experienced in the duties they are expected to carry out and/or receive any needed training.

D. The quality assurance system shall be reviewed annually by management to ensure its continued effectiveness. Such reviews shall be documented with details of any changes.

E. Standard operating procedures (SOPs) shall be kept in a manual available to the analyst and the inspector. SOPs may be included as a part or section of the laboratory's quality assurance manual. The laboratory shall have clearly defined, written SOPs or an equivalent, addressing, at a minimum, and as appropriate:

1. methods of analysis;

2. sample collection, preservation, storage, handling, and chain of custody;

3. procurement and inventory procedures;

4. preventive maintenance;

5. recordkeeping and record storage (archives);

6. data reduction, validation, and reporting;

7. correcting erroneous reports;

8. management of laboratory wastes and hazardous materials; and

9. complaints registered against the laboratory's testing procedures, reporting procedures, and/or other general operating procedures.

F. Supervisory staff shall be responsible for quality assurance/quality control implementation and compliance.

G. The following general quality control principles shall apply, where applicable, to all testing laboratories. The manner in which they are implemented is dependent on the types of tests performed by the laboratory (e.g., chemical, microbiological, radiological). The standards for any given test type shall assure that the following applicable principles are addressed:

1. all laboratories shall have protocols in place to monitor the following quality controls:

a. adequate controls to monitor tests such as blanks, spikes, or reference toxicants;

b. adequate tests to define the variability and/or reproducibility of the laboratory results such as duplicates;

c. measures to ensure the accuracy of the test data, including sufficient calibration and/or continuing calibrations, use of certified reference materials, proficiency test samples, or other measures;

d. measures to evaluate test performance, such as method detection limits, or range of applicability such as linearity;

e. selection of appropriate formulae to reduce raw data to final results such as linear regression, internal standards, or statistical packages;

f. selection and use of reagents and standards of appropriate quality; and

g. measures to assure constant and consistent test conditions (both instrumental and environmental) where required by the method, such as temperature, humidity, light, or specific instrument conditions;

2. all quality control measures shall be assessed and evaluated on an ongoing basis, and quality control acceptance limits shall be used to determine the validity of the data. The acceptance/rejection criteria shall be updated at a frequency established by the method or by the department’s standards;

3. the laboratory shall have procedures for the development of acceptance/rejection criteria where no method or regulatory criteria exists; and

4. the method-specified and/or method-recommended quality control protocols shall be followed. The essential standards shall be used if no protocols are written into the method or if the method protocols are less stringent.

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§5303. Equipment and Supplies

A. The laboratory shall be furnished with or have access to all items of equipment required for correct performance of the analytical procedures for which it is accredited.

B. All equipment shall be properly maintained. Maintenance shall be documented.

C. Defective equipment shall be removed from service and labeled until it has been repaired and shown to function satisfactorily.

D. Maintenance log book(s) shall be maintained for all major equipment. Each log shall include:

1. the name of the item of equipment;

2. the manufacturer's name, type identification, and serial number;

3. the date received and the date placed in service;

4. the condition of equipment when placed in service (new, used, or reconditioned);

5. the current location;

6. the location of manufacturer's instruction manual (if available); and

7. the details of maintenance.

E. In the case of measuring equipment, calibration records shall be maintained.

F. Records shall be maintained for acquisition of all equipment, reagents, and support services utilized by the laboratory in the generation of analytical data.

G. Supplies used for environmental testing shall meet the following minimums:

1. analytical reagents:

a. analytical reagent grade (AR) chemicals or equivalent are acceptable, unless individual procedures specify other reagent requirements;

b. stock and working standard solutions shall be checked regularly for signs of decomposition and expiration;

c. all solutions shall be labeled with identification of the compound, concentration, date prepared, analyst who prepared solution, and expiration date;

d. all purchased chemicals, solutions, and standards shall be labeled with dates of receipt, the dates of expiration on the container, and the date when the container is opened;

e. when reagents are removed from a container, they shall be used entirely or the unused portion discarded. Unused portions of a reagent may not be returned to the original container; and

f. compressed gases shall be of commercial grade, unless individual procedures specify other requirements.

2. glassware shall be cleaned and maintained properly as required by the test methodology; and

3. thermometers:

a. the laboratory shall have access to a NIST (National Institue of Standards and Technology) traceable thermometer where applicable;

b. the calibration of working thermometers, with the exception of dial thermometers, shall be checked at least annually against a NIST traceable certified thermometer and results recorded and documented per thermometer;

c. the calibration of dial-type thermometers shall be checked at least quarterly against a NIST traceable thermometer and results recorded per thermometer; and

d. thermometers shall be labeled when calibrated and the correction factor recorded.

H. Equipment used for environmental testing shall meet the following minimums:

1. analytical balances/pan balances:

a. records of balance calibration shall be kept for at least two ranges with a minimum class S or S-1 reference weights or equivalent (weights should be recertified every two years). Records showing daily (or before each use) functional/calibration checks for analytical balances and monthly functional/calibration checks for pan balances shall be maintained;

b. balances shall be calibrated and serviced at a minimum of once per year and service date recorded on the balance; and

c. balances may only be used with suitable support;

2. pH meters:

a. the laboratory shall use a pH meter with appropriate electrode with scale graduations at least 0.1 pH units (calibrated to ± 0.1 pH units for each use period) with temperature correction;

b. either a thermometer or a temperature sensor for automatic compensation shall be in use;

c. records shall be maintained indicating calibration daily or before each use, whichever is less frequent; and

d. aliquots of standard pH 4 and pH 7 or pH 7 and pH 10 shall be used only once;

3. conductivity meter:

a. a conductivity meter and probe of sufficient sensitivity shall be in use;

b. records shall be kept to show a daily or before each use calibration check, whichever is less frequent. Calibration shall be within the range of interest using standard solutions; and

c. records shall be kept showing that the cell constant is determined annually;

4. refrigeration equipment:

a. thermometer(s) in each refrigerator shall be immersed in liquid to the appropriate immersion line;

b. thermometers shall be graduated in increments no larger than 1°C;

c. temperatures for each refrigerator shall be recorded for each day in use for laboratory activities;

d. samples shall be stored in separate refrigerators from all standards where a potential for cross-contamination exists; and

e. refrigerator temperature should be maintained ~~at 4°C ± 2°C~~ between 1°C and 6°C(inclusive), and freezer temperature shall be less than 0°C;

5. visual comparison devices:

a. visual devices shall be calibrated according to manufacturer's specifications and/or test methodologies; and

b. results shall be recorded and maintained; and

6. ovens/incubators/baths:

a. temperature shall be adequately controlled; and

b. records shall be kept to show that temperature is maintained (e.g., beginning and end of each use cycle or daily for extended drying periods).

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§5305. Calibration

A. Measuring and testing equipment used by the testing laboratory shall be calibrated, where appropriate, before being put into service and thereafter according to an established program.

B. The overall program of calibration of equipment shall be designed and operated so as to ensure that measurements made in the testing laboratory are traceable (where the concept is applicable) to national standards of measurement and, where available, to international standards of measurement specified by the International Committee of Weights and Measures. Where the concept of traceability to national or international standards of measurement is not applicable, the testing laboratory shall provide satisfactory evidence of correlation or accuracy of test results (e.g., by participation in a suitable program of interlaboratory comparisons).

C. The laboratory shall record all calibration data including frequency, conditions, and standards used for all analytical methodology.

D. The laboratory shall verify and document all standards versus primary (reference) standards.

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§5307. Test Methods and Procedures

A. The laboratory shall have procedures for making and controlling revisions to in-house SOPs, using revised SOPs only after written authorization from the designated laboratory authority.

B. Quality control procedures shall be documented and available to the staff as required in LAC 33:I.5301.C.

C. All manual calculation and data transfers shall be subject to appropriate checks.

1. When manual calculations are checked by a supervisor or another analyst, the results shall be initialed and dated on the work sheet by the individual who verified the results.

2. Where results are derived by electronic data processing techniques, the stability of the system shall be such that the accuracy of the results is not affected. This generally implies an ability to detect malfunctions in the hardware during program execution and take appropriate corrective action. Adherence to good automated laboratory practices (GALP)is recommended; however, at a minimum the laboratory must comply with the following:

a. computer software must be appropriate for the intended use;

b. procedures must be established and implemented for the protection of the integrity of data. Such procedures shall include:

i. integrity of data entry or capture;

ii. data storage;

iii. data transmission; and

iv. data processing;

c. computer and automated equipment must be provided with acceptable environmental operating conditions in order to maintain the operating integrity of the system; and

d. appropriate procedures must be implemented in order to maintain the security of data. These procedures must include prevention of unauthorized access to computer records and prevention of unauthorized amendments or changes to computer records.

D. Whenever samples are subcontracted to another environmental testing laboratory, the original laboratory shall maintain a verifiable copy of results with a chain of custody. This procedure may not be used to circumvent proper accreditation or any state requirements. The original laboratory is responsible for ensuring that the secondary laboratory used is properly accredited for the scope of testing performed.

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§5309. Radiochemistry and Radionuclide Assay

A. General Requirements. Radiochemistry and radionuclide assay laboratories shall be subject to the requirements set forth throughout these regulations and to those specific requirements established in this Section. These are minimum specifications, and more stringent criteria may be utilized.

B. Quality Control Practices

1. The laboratory shall continually evaluate its performance for each method and matrix that includes the determination of accuracy and precision.

2. Supervisory personnel shall conduct a documented review of the data calculations and quality control (QC) results.

3. Deviations or deficiencies shall be reported to management and documented. QC data shall be retrievable for all analyses.

4. Method detection limits shall be determined and documented. Confirmation of detection limits shall be done yearly or as required by the method.

C. Quality Assurance Checks

1. Radiochemistry and Associated Radionuclide Assay. Ten percent of all analyses shall be QC, unless otherwise specified by the specific method. A minimum of three QC samples should be performed for each batch. The lab should repeat all samples if the QC check standard is outside the 95 percent confidence interval (± two standard deviations). Samples should be performed as follows:

a. QC samples should include one spike in 10 or one spike per batch if less than 10;

b. QC samples should include one blank in 10 or one blank per batch if less than 10;

c. QC samples should include one duplicate or spiked duplicate in ~~20~~ 10 or one duplicate per batch if less than ~~20~~ 10; and

d. spike samples should be representative of specified regulatory limits and/or they should approach the method-specific minimum detectable activities or lower limit of detections.

2. Radionuclide Assay Other than Radiochemistry. ~~Twenty~~ Ten percent of all analyses shall be QC, unless otherwise specified by the method. A minimum of three QC samples should be performed for each batch. The lab should repeat all samples if the QC check standard is outside the 95 percent confidence interval ± two standard deviations. Samples should be performed as follows:

a. QC samples should include one spike in ~~20~~ 10 or one spike per batch if less than ~~20~~ 10;

b. QC samples should include one blank in ~~20~~ 10 or one blank per batch if less than ~~20~~ 10;

c. QC samples should include one duplicate or spiked duplicate in ~~20~~ 10 or one duplicate or spiked duplicate per batch if less than ~~20~~ 10;

d. spike samples should be representative of specified regulatory limits and/or they should approach the method-specific minimum detectable activities or lower limit of detections; and

e. standard NIST traceable sources may be substituted for spike analysis.

D. General Equipment and Supplies

1. Supplies

a. Distilled and/or deionized water shall be demonstrated to be free of interferants at applicable detection limits. This may be accomplished through the use of blanks.

b. Analytical reagents shall be demonstrated to be free of interferants at applicable detection limits. This may be accomplished through the use of blanks.

c. Reference sources should be traceable to NIST or an equivalent and shall be replaced after an appropriate period of time, not to exceed five half-lives of a single nuclide or, in the case of mixed nuclide standards, they should be replaced after they have been determined to be unusable. Unusable is determined by the inability to meet calibration criteria as set forth by the method or technical manual.

2. Equipment - Auto Pipetors/Diluters

a. Apparatus having sufficient sensitivity for the application shall be used.

b. Records shall be kept showing delivery volumes are checked periodically.

c. Laboratory technicians shall periodically demonstrate the ability to properly use the equipment. This shall be documented.

E. Analytical Instrumentation. Maintenance log book(s) shall be maintained on all instrumentation or measuring devices. Each log shall include:

1. information as set forth in LAC 33:I.5303.D;

2. calibration frequency;

3. standards used for calibration;

4. calibration history;

5. the authorized calibration personnel or institute; and

6. records of all maintenance performed.

F. Environmental Testing Equipment. Equipment used for environmental testing shall meet the following minimums:

1. low background alpha/beta counting systems:

a. the systems shall be calibrated at least yearly;

b. the systems shall be calibrated in accordance with the appropriate methodologies or their appropriate technical manual;

c. attenuation curves shall be developed for appropriate alpha/beta energies that best represent the energies of the radionuclide of concern;

d. voltage plateaus shall be performed yearly, whenever counting gas has been changed, or if major maintenance is performed to the system. If the voltage plateau changes by more than 50 volts, the calibration curves shall be performed;

e. daily backgrounds and reference source checks shall be performed when in use or weekly when not in use; and

f. sample log books shall be maintained for all samples that were counted/analyzed on the appropriate systems;

2. gamma spectroscopy systems:

a. the systems shall be calibrated at least yearly and shall include energy, peak width, and efficiency;

b. the systems shall be calibrated according to the appropriate methodologies or the manufacturer’s technical manual;

c. daily reference source checks shall be performed when in use or weekly when not in use;

d. monthly background checks ~~should~~ shall be performed; and

e. sample log books shall be maintained for all samples that were counted/analyzed on the appropriate systems;

3. liquid scintillation systems:

a. the systems shall be calibrated at least yearly and shall include energy, peak width, and efficiency;

b. the systems shall be calibrated according to the appropriate methodologies or the manufacturer’s technical manual;

c. daily backgrounds and reference source checks shall be performed when in use or weekly when not in use; and

d. sample log books shall be maintained for all samples that were counted/analyzed on the appropriate systems;

4. alpha spectroscopy systems:

a. the systems shall be calibrated at least yearly;

b. the systems shall be calibrated according to the appropriate methodologies or the manufacturer's technical manual;

c. daily reference source checks shall be performed when in use or weekly when not in use;

d. monthly background checks shall be performed; and

e. sample log books shall be maintained for all samples that were counted/analyzed on the appropriate systems; and

5. analytical instrumentation not mentioned above, such as counter scalers or ionizing radiation detection equipment:

a. the instrumentation shall be calibrated at least yearly or as mandated by a specific regulatory agency such as EPA, Nuclear Regulatory Commission (NRC), or state governments;

b. the instrumentation shall be calibrated according to the appropriate methodologies or to the manufacturer's technical manual;

c. daily backgrounds and reference source checks shall be performed when in use or weekly when not in use, if applicable; and

d. sample log books shall be maintained for all samples that were counted/analyzed on the appropriate systems.

G. Laboratory Environment

1. Radiochemistry and radionuclide assay counting rooms, wet chemistry rooms, and sample preparation and sample storage rooms shall be physically separated. Access and egress shall be controlled.

2. Radiochemistry and radionuclide assay counting rooms shall be adequately monitored for room temperature, humidity, pressure, and electrical supply characteristics on a daily basis when in use. These characteristics shall be maintained to ensure proper operation of the analytical equipment. Records shall be maintained.

3. Adequate measures shall be taken to ensure good housekeeping in the laboratory.

H. Waste Disposal. Radioactive waste disposal shall be thoroughly documented. The documentation shall include the following:

1. quantity disposed of;

2. where the radioactive material was disposed;

3. when it was disposed;

4. who disposed of the material; and

5. activity of disposed material, as applicable.

I. Records (Control Charts)

1. Control charts shall be updated at least monthly.

2. Copies of the control charts shall be available for technician review.

3. Control charts shall have at a minimum the following information:

a. all axes labeled;

b. instrument I.D. and/or serial number;

c. one and two sigma values as well as the normal expected values; and

d. applicable units as necessary.

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§5311. Quality Assurance for Biomonitoring Laboratories

A. Quality assurance practices for toxicity testing laboratories must address all activities that affect the quality of the final effluent toxicity data, such as:

1. effluent sampling and handling;

2. the source and condition of the test organisms;

3. condition of equipment;

4. test conditions;

5. instrument calibration;

6. replication;

7. use of reference toxicants;

8. recordkeeping; and

9. data evaluation.

B. Facilities, Equipment, and Test Chambers

1. Separate test organism culturing and toxicity testing areas shall be provided to avoid loss of cultures to cross-contamination. Ventilation systems shall be designed to prevent recirculation of air from chemical analysis laboratories into organism culturing or testing areas and from sample preparation areas into culture rooms.

2. Laboratory and toxicity test temperature control equipment shall be adequate to maintain recommended test water temperatures.

3. Recommended materials shall be used for test equipment and test chambers.

C. Laboratory Water Used for Culturing and Test Dilution Water

1. The dilution water used in effluent toxicity tests will depend on the objectives of the study or requirements of discharge permits.

2. Water used for culturing organisms, dilutions, and internal quality assurance tests with food, organisms, and reference toxicants shall be analyzed for toxic metals and organics annually or whenever difficulty is encountered meeting minimum acceptability control requirement. The concentration of the metals Al, As, Cr, Co, Cu, Fe, Pb, Ni, and Zn, expressed as total metals, shall not exceed one ug/L each, and Cd, Hg, and Ag, expressed as total metals shall not exceed 100 ng/L. Total organochlorine pesticides plus PCBs shall be less than 50 ng/L. Pesticide levels shall not exceed EPA's ambient water quality chronic criteria values where available.

3. Water used for culturing and test dilutions shall be prepared using methods in the test manuals.

D. Sample holding times and temperatures of effluent samples must conform to conditions described in the test methods and/or the discharge permit.

E. Test Conditions

1. Water temperature shall be maintained within limits specified for each test.

2. ~~Test chambers/rooms~~ Environmental chambers, incubators or equivalent facilities shall be adequately monitored by utilizing a seven-day continuous recording chart for temperature and light/dark cycle. Verification that the light/dark cycle is maintained shall be done at a minimum of twice monthly if a recording device is not utilized. Temperature recording charts shall be maintained in record form.

F. Test Organism Quality

1. If the laboratory does not maintain in-house cultures of test organisms and obtains organisms from an outside source, the sensitivity of each batch of test organisms shall be determined with the appropriate reference toxicant test performed concurrently with the effluent test, unless the organism supplier provides control chart data from, at a minimum, the last five monthly reference toxicity tests.

2. If the laboratory maintains in-house cultures, the sensitivity of the offspring shall be determined with the appropriate toxicity test performed with a reference toxicant at least once each month. If a given species of test organisms is used only monthly, or less frequently, in toxicity tests, a reference toxicant test shall be performed with each effluent and/or receiving water toxicity test.

3. If the laboratory maintains in-house cultures, records shall be maintained on organism health, mortality, water quality, and culture system maintenance.

4. Test organisms shall be positively identified to species.

G. Food Quality

1. Problems with nutritional suitability of food will be reflected in the survival, growth, and reproduction in cultures and toxicity tests. Artemia cysts and other foods shall be obtained and analyzed as described in the test manuals, unless analysis is provided by the supplier, then the certificate of analysis shall be maintained.

2. New batches of food used in culturing and testing should be analyzed for toxic organics and metals or whenever difficulty is encountered meeting minimum acceptability criteria for control survival and reproduction or growth. Foods exceeding the requirements in the test manuals should not be used.

H. Test Acceptability

1. A control shall be run with each toxicity test.

2. The minimum criteria stated in the appropriate test manuals and/or the discharge permit must be met for a test to be valid.

3. Individual tests may be conditionally acceptable if temperature, dissolved oxygen (DO), and other specified conditions fall outside specifications, depending on the degree of departure and objectives of the test. The acceptability will depend on the experience and professional judgement of the laboratory investigator and reviewing staff of the regulatory agency.

I. Analytical methods for analyses of culture and dilution water, food, and test solutions must include established quality assurance practices outlined in EPA manuals (USEPA 1979a and USEPA 1979b).

J. Calibration and Standardization

1. Instruments used for routine measurements of chemical and physical parameters such as pH, DO, temperature, and conductivity must be calibrated and standardized according to the instrument manufacturer's procedures as indicated in LAC 33:I.5301 on quality assurance. Calibration data is recorded in a permanent log book.

2. Wet chemical methods used to measure hardness, alkalinity, and total residual chlorine must be standardized prior to use each day according to the procedures for these specific EPA methods.

K. The minimum number of replicates stated in the test methods and/or permit shall be used for each toxicity test.

L. It is the laboratory's responsibility to demonstrate its ability to obtain consistent, precise results with reference toxicants before it performs toxicity tests with effluents for permit compliance purposes. To meet this requirement, the intralaboratory precision, expressed as percent coefficient of variation (CV%), of each type of test used in the laboratory shall be determined by performing five or more tests with different batches of test organisms, using the same reference toxicant at the same concentrations, with the same test conditions and the same data analysis methods. A reference toxicant concentration series (0.5 or higher) shall be selected that will consistently provide partial mortalities at two or more concentrations.

M. Documenting Ongoing Laboratory Performance

1. Satisfactory laboratory performance shall be demonstrated by performing one acceptable test per month with a reference toxicant for each test method used in the laboratory. For a given test method, successive tests must be performed with the same reference toxicant, at the same concentrations, in the same dilution, and using the same data analysis methods.

2. A control chart should be prepared for each combination of reference toxicant, test species, test conditions, and end points. Control limits are stated in test method manuals.

N. Reference toxicants such as sodium chloride (NaCl), potassium chloride (KCl), cadmium chloride ($CdCl_2$), copper sulfate ($CaSO_4$), sodium dodecyl sulfate (SDS), and potassium dichromate ($K_2Cr_2O_7$) are suitable for use by the laboratory. Standard reference materials can be obtained from commercial supply houses or can be prepared in-house using reagent grade chemicals.

O. A complete file shall be maintained for each individual toxicity test or group of tests on closely related samples. Original data sheets shall be signed and dated by the personnel performing the tests. The file should contain:

1. a record of the chain of custody;

2. a copy of the sample log sheet;

3. the original bench sheets;

4. chemical analysis data on the sample(s);

5. detailed records of the test organisms used in the test, such as species, source, age, date of receipt, and other pertinent information relating to their history and health;

6. information on calibration of equipment and instruments; and

7. results of reference toxicant tests.

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§5313. Reports

A. The work carried out by the testing laboratory shall be covered by a report that accurately, clearly, and unambiguously presents the test results and all other relevant information. The report format should be specifically designed for the type of test/analysis reported, but standardized headings should be utilized whenever possible.

B. Each test report shall include at least the following information:

1. name and address of testing laboratory;

2. title of report, unique identification of report (such as log number), identification of each page of the report by number, and total number of pages in the report;

3. description and identification of the sample(s);

4. date of receipt of sample(s) and date(s) of performance of test, as appropriate;

5. identification of the test method;

6. any deviations, additions to, or exclusions from the test method and any other information relevant to a specific test;

7. disclosure of any nonstandard test method utilized;

8. measurements, examinations, and results, accompanied by appropriate quality assurance(QA) documents;

9. a statement on measurement uncertainty (where relevant);

10. a signature and title of person(s) accepting technical responsibility for the test report and date of issue;

11. if applicable, a statement that indicates that the results relate only to the items tested; and

12. if applicable, a statement that indicates that the report shall not be reproduced in full (or in part, if required) without the written approval of the customer.

C. Corrections or additions to a test report after issue shall be made only by a further document suitably marked (e.g., "Supplement to test report log number ..." or as otherwise identified) and shall meet the relevant requirements of this Section.

D. In instances where the laboratory transmits a report via telephone, telex, facsimile (FAX), or any other means of electronic transmittal, the laboratory must have in place a written procedure that will provide protection and/or preservation of client confidentiality.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of the Secretary, LR 24.

§5315. Records

A. The testing laboratory shall retain on record all raw data and observations, calculations and derived data, calibration records, and the final test report for a minimum of five years or as required by regulatory or legal requirement.

B. All records and test reports shall be held securely and in confidence to the client, unless otherwise required by law.

C. The testing laboratory shall maintain a system that provides for retrievability of the chain of custody of the sample source, the analytical method, results (including calibration and instrument checks), the analyst performing the analysis, and the date. If laboratory records indicate that incorrect or questionable data has been generated by defective or improperly operated equipment, erroneous data entry, or other such anomalies, and a report has been issued, then the laboratory shall immediately notify the client. A written, corrected or amended report must be forwarded to the client.

D. Current reference documents (e.g., EPA manuals, CFRs, Standard Methods) shall be maintained and available to the staff.

E. Entries to all laboratory analytical records shall be made in a legible, permanent fashion and corrections made without obliterating original entries. All corrections shall be initialed and dated.

F. A permanent record of employees' signatures and initials shall be maintained.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of the Secretary, LR 24.

Title 33
ENVIRONMENTAL QUALITY

Part I. Office of the Secretary
Subpart 3. Laboratory Accreditation

Chapter 55. Sample Protocol/Sample Integrity

§5501. Unacceptable Samples

When a sample is received by the testing laboratory and it is apparent or suspected that the sample protocol has not been followed, the laboratory should have a written procedure for handling of the questionable sample. The laboratory may choose to notify the customer and either request another sample or, if the customer insists upon analysis of the sample, reserve the right to include a disclaimer in the final report identifying the sample anomaly. This disclaimer must be permanently attached to the final report.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of the Secretary, LR 24.

Title 33
ENVIRONMENTAL QUALITY

Part I. Office of the Secretary
Subpart 3. Laboratory Accreditation

Chapter 57. Maintenance of Accreditation

§5701. Display of Accreditation Certificate

A. A current accreditation document shall be displayed at all times in a location visible to the public in each accredited laboratory. In cases of suspension or discreditation, the document shall be immediately removed.

B. The accreditation documents shall note the scope of accreditation (classes/parameters of approved testing) as well as the time frame for which the laboratory is accredited.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of the Secretary, LR 24.

§5703. Renewal of Accreditation

A. Accreditation shall be renewed annually, provided the testing laboratory has maintained compliance with these regulations, has reported acceptable proficiency test values for accredited classes, and has paid appropriate fees.

B. Failure to receive a renewal notice does not exempt laboratories from meeting the renewal date requirements.

C. Failure to pay the required renewal fees for 30 days shall automatically suspend accreditation of the laboratory until the fee is received by the department.

D. Failure to pay the required renewal fees for 90 days shall automatically result in discreditation of the laboratory. A laboratory whose accreditation has expired may reapply.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of the Secretary, LR 24.

§5705. Discreditation and Suspension

A. The department may suspend or discredit a laboratory in any or all test categories when the laboratory fails to fully meet all requirements of these regulations. Factors such as the gravity of the offense, the danger to the public of the offense, the intent of the violation, the extent of the violation, and the proposed correction of the problem will be considered to determine if suspension or discreditation is to be imposed. An emergency order immediately discrediting the laboratory may be issued if any conditions exist that present an eminent danger to public health and safety.

B. The department shall notify the laboratory by registered or certified letter of the suspension or discreditation and the reasons for the action.

C. Suspensions shall not be withdrawn until the basis for the suspension has been eliminated or rectified.

D. Appeals for laboratoris that have received discreditation notices are governed by applicable statutes.

E. If the testing laboratory's accreditation is revoked by the department or another agency having primary enforcement responsibility or delegated administrative responsibility (e.g., out-of-state laboratories), the laboratory management shall notify, in writing, all clients that utilize the laboratory for analysis of samples and reporting of data to the department that the laboratory's accreditation has been revoked. Clients must be advised of the change in accreditation status within 10 calendar days from the official notice of the action.

F. The following shall be considered grounds for discreditation/suspension:

1. violation of a condition of the accreditation;

2. violation of a statute, regulation, or order of the department;

3. misrepresentations or falsifications made to the department, including any documents associated with accreditation applications;

4. demonstrable nonconformance with the requirements of these regulations, including failure to correct deficiencies;

5. nonpayment of applicable fees;

6. demonstrating incompetence or making consistent errors in analyses or erroneous reporting;

7. failure to report, in writing within 30 days, any changes in location, ownership, management and supervisory staff, authorized representative, major facilities of the laboratory, modification of technique, or any revisions to the accreditation application or required support documentation;

8. failure to employ approved testing methods in the performance of analyses;

9. failure to maintain facilities or equipment properly;

10. failure to report analytical test results as required or to maintain required records of test results;

11. failure to participate successfully in a required performance evaluation program;

12. violation or aiding and abetting in the violation of any provision of these regulations or the rules promulgated hereunder;

13. advertising false credentials;

14. failure to indicate clearly in the records when analyses were subcontracted to another laboratory;

15. performing and charging for additional tests or analyses that have not been requested by the customer, falsifying analyses, or engaging in other unethical or fraudulent practices; and

16. subcontracting performance evaluation samples to another laboratory and using the results to satisfy requirements for accreditation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of the Secretary, LR 24.

§5707. Changes in Laboratory Operation

Changes in laboratory name, ownership, location, personnel, facilities, methodology, or any factors significantly affecting the performance of analyses for which the laboratory was originally accredited shall be reported to the department within 30 days.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of the Secretary, LR 24.

§5709. Reaccreditation

Reaccreditation shall require the submission of a new, revised application demonstrating and documenting corrective action implemented since loss of accreditation status.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2011.
HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of the Secretary, LR 24.